

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and	)	<b>REDACTED</b>
BOSTON SCIENTIFIC SCIMED, INC.,	)	<b>PUBLIC VERSION</b>
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 05-768-SLR
	)	
CONOR MEDSYSTEMS, INC.,	)	
	)	
Defendant.	)	

**OPENING BRIEF IN SUPPORT OF CONOR MEDSYSTEMS'  
MOTION FOR SUMMARY JUDGMENT OF  
NONINFRINGEMENT OF CLAIM 35 OF THE JANG '021 PATENT**

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## **INTRODUCTION**

Conor Medsystems, Inc. ("Conor") respectfully submits this brief in support of its motion for summary judgment: (1) that BSC has not shown infringement for Conor stent designs that BSC did not identify as accused products and which never have been sold anywhere, and (2) that Conor's CoStar and UniStar stents do not infringe claim 35 of Dr. Jang's U.S. Patent No. 5,922,021 (the "'021 patent") literally or under the doctrine of equivalents.

## **STATEMENT OF UNCONTESTED FACTS**

### **A. The CoStar & UniStar Stents**

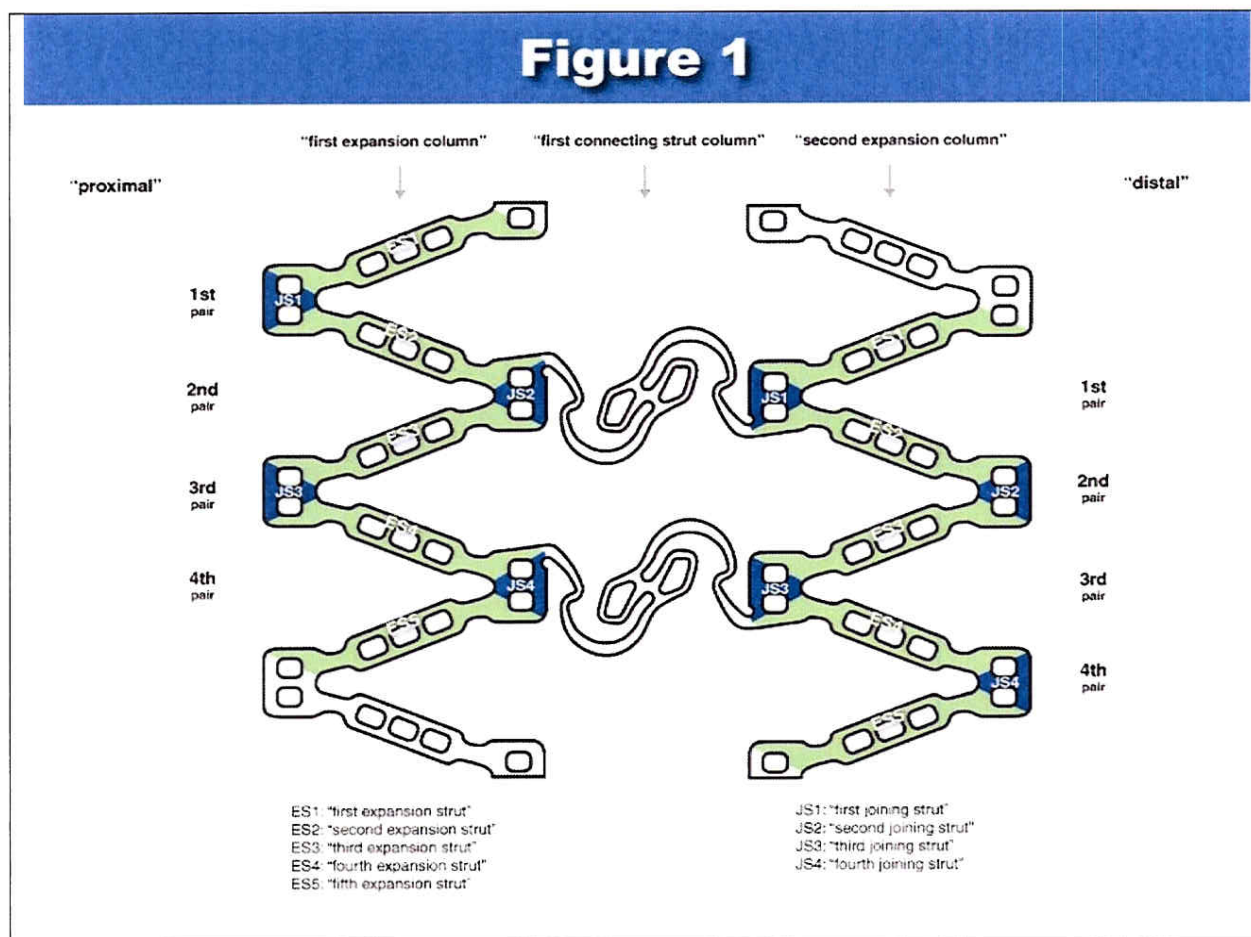
Conor's CoStar and UniStar stents have the same stent architecture. The difference between the two is that the CoStar stent is used to deliver drug; the UniStar is not loaded with any drug. Aside from the drug, the architecture of the CoStar and UniStar is the same. For convenience, the following discussion uses the term "CoStar" to refer to both the CoStar and UniStar stents.

The CoStar stent has connectors that link strut pairs that are aligned and face in opposite directions in a 180 degree out-of-phase design in which the connected struts are aligned rather than offset. A photograph of the CoStar stent is shown on the right.



BSC's expert Prof. James Moore has agreed that the CoStar stent has a 180 degree out-of-phase design. See, e.g., Ex. A ¶ 22 ("[T]he CoStar stent . . . has expansion columns that

are 180 degrees out-of-phase . . ."). In his expert report, Prof. Moore used the following schematic of the CoStar stent to illustrate his infringement analysis (Ex. B ¶ 23 & Ex. L):



## B. Conor's Other Stent Designs

Conor was founded in 1999 (as a reincorporation of Conor Technology, which was founded in 1995). Ex. C at Tr. 24:20-25:22. Since its inception, Conor has worked on developing and commercializing a stent specifically designed to deliver drugs. See Ex. D col. 14:32-38. After several design iterations, Conor settled upon a stent design to commercialize. The design Conor settled on is known as the CoStar when coated with drug. The bare-metal version, which is not sold commercially, is known as the UniStar. Conor's only commercial

product is the CoStar stent, which has only been sold outside of the United States. See Ex. E at 16-17

Conor began selling its CoStar stent in certain countries outside of the United States in February 2005. **REDACTED**; Ex. G. On February 24, 2006, the CoStar stent received a CE Mark (approval for the European Economic Area) and then began selling its CoStar stent in Europe. **REDACTED** Ex. H.

**REDACTED**

On November 8, 2005, BSC sued Conor for infringement of the Jang '021 patent. BSC alleged that

Conor has infringed the '021 patent by making, using, offering to sell and/or selling within the United States stents (including but not limited to those using the names "CoStar" or "UniStar" as all or part of the trademark) as claimed thereby ("the Accused Stents"), and/or inducing and/or contributing to such conduct, without authority and in violation of 35 U.S.C. § 271(a), (b) and/or (c).

(D.I. 1 ¶ 9.) The complaint does not identify *any* accused products other than the CoStar and UniStar stents.

In its interrogatories, Conor asked BSC to "describe in detail each product or apparatus (including, without limitation, product and model numbers) by which Boston Scientific contends Conor has infringed or is infringing [the patent claims at issue]." Ex. I at 5. In response, BSC eventually identified "Conor stents including those using the names 'CoStar' or 'UniStar' as all or part of the trademark." Ex. J at 3. Again, BSC did not identify *any* accused products other than the CoStar and UniStar stents.

While BSC continued to supplement other interrogatory responses up to and including a supplement to several interrogatory responses filed on March 9, 2007 (the last day of



fact discovery), it never further supplemented its response to Interrogatory No. 2. See Ex. K. In its March 9 supplemental responses, BSC supplemented its response to Conor Interrogatory No. 3, which asked for:

all facts that support or relate to your allegation that Conor is infringing the '021 Patent, including the contention that Conor is "making, using, offering to sell and/or selling some or all of the Accused Stents for subsequent commercial sale in India and other countries and/or [sic] the development and submission of information other than under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

Ex. K at 3. In its over-four-page response, BSC repeatedly refers to "the accused CoStar and UniStar stents" and makes absolutely no reference to any other stent designs. Id. at 5-9.

On March 19, 2007, after fact discovery closed and after having not identified any accused stents other than the CoStar and UniStar stents, BSC submitted an expert report on infringement from Dr. James E. Moore (the "Moore Report"). In the report, Dr. Moore opines that the CoStar and UniStar stents infringe claim 35 of the '021 patent. Ex. B ¶¶ 23-25. He also identifies numerous other drawings and pictures, which he describes as "related" or "previous" Conor stent designs, as infringing. Id. ¶ 26. He purports to identify these other designs by citing drawings and pictures of stent designs as examples:

*see, e.g.*, CM 003282; CM 003292; CM 003295-96; CM 003319-20; CM 003321-22; CM 003364-65; CM 003366-67; CM 058215, CM 006890; CM 009886-87; CM 107551, CM 118758, CM 118760, CM 118767, CM 118784, CM 118844-45, CM 118931, CM 123949, CM 123950, CM 124264, CM 125112; CM 020458; CM 058476-77; CM 090066; CM 119000; CM 129935 and BSC-C 85073) (*see* Exhibit C).

Id. ¶ 8(C). These "related" or "previous" designs were not listed in the complaint as accused products, and they were not identified as accused products in BSC's interrogatory responses.



Prof. Moore does not cite any evidence that the stents depicted in the cited drawings and pictures were ever sold or offered for sale anywhere in the world.

The entirety of Prof. Moore's infringement analysis for these designs is:

Certain of Conor's related stent designs . . . similarly include alternating expansion columns connected to connector columns in the manner claimed by the Jang '021 patent. My infringement analysis regarding the CoStar stent is therefore equally applicable to at least these related Conor stent designs.

Ex. B ¶ 26.

### **SUMMARY OF ARGUMENT**

BSC attempts to improperly accuse Conor stent designs other than the CoStar and UniStar designs of infringement – citing drawings and pictures. BSC did not identify *any* of these other designs as "accused products," either in its complaint or in its interrogatory responses. Moreover, none of them is a "product" in any meaningful sense. Indeed, none of these other designs ever became a commercialized product, and BSC has no evidence that any of them was ever offered for sale. In addition, BSC's expert has not provided an infringement analysis with respect to any of them. As such, it has failed to meet its burden of coming forward with evidence of infringement. Accordingly, summary judgment of non-infringement with respect to Conor's other stent designs is proper.

If the Court construes the asserted claim as requested by Conor, there can be no infringement by any Conor stent. There is no dispute that the CoStar stent has connectors linking expansion strut pairs that are aligned and face in opposite directions in a 180 degree out-of-phase design. As demonstrated in the Markman brief that Conor is filing on this date, such designs are outside the scope of claim 35 under the proper construction of the "wherein" of claim 23 of the '021 patent (from which claim 35 depends).

Moreover, under Festo, BSC cannot assert infringement of the "wherein" clause under the doctrine of equivalents ("DOE"). During prosecution, Jang added the "wherein" clause by amendment to both of his independent claims (issued claims 1 and 23) in order to overcome a rejection based on the prior art. BSC cannot overcome the resulting presumption of prosecution history estoppel, and therefore cannot assert infringement under the DOE.

## ARGUMENT

### I. THE SUMMARY JUDGMENT STANDARD

The "salutary procedure" of summary judgment is just "as appropriate in a patent case as in any other." Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd., 731 F.2d 831, 835 (Fed. Cir. 1984); Nike Inc. v. Wolverine World Wide, Inc., 43 F.3d 644, 646 (Fed. Cir. 1994).

"A determination of infringement requires a two-step analysis. The court must determine (1) 'the scope and meaning of the patent claims asserted,' and (2) how 'the properly construed claims . . . compare[] to the allegedly infringing device.'" Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1369 (Fed. Cir. 2004) (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (*en banc*)). The first step is an issue of law for the court; the second step is an issue of fact. However, "[w]here the parties do not dispute any relevant facts regarding the accused product, ... [and merely] disagree over possible claim interpretations, the question of literal infringement collapses into claim construction and is amenable to summary judgment." Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 983 (Fed. Cir. 1997).

The burden of proving patent infringement falls on the patentee. Cammeyer v. Newton, 94 U.S. 225, 231 (1876). "It is implicit that identification of the accused device is a necessary prerequisite to determining infringement. Without identification of an accused device, the plaintiff cannot determine if the claims read on the device." Eon-Net, L.P. v. Flagstar

Bancorp, Inc., 239 F.R.D. 609, 615 (W.D. Wash. 2006); see also Kim v. Sara Lee Bakery Group, Inc., 412 F. Supp. 2d 929, 933-34 (N.D. Ill. 2006). "[H]owever, it is insufficient to merely identify a product and claim that it infringes." Eon-Net, L.P. v. Flagstar Bancorp, Inc., 2006 WL 2350176, at \*4 (W.D. Wash. Aug. 11, 2006). After identifying the accused product, the patentee must prove that "all of the elements of the [asserted] claim, as correctly construed, [are] present in the accused" product. TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1371 (Fed. Cir. 2002).

Summary judgment of noninfringement is appropriate "where the [patent owner's] proof is deficient in meeting an essential part of the applicable legal standard [for infringement], since such failure renders all other facts immaterial." London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1537 (Fed. Cir. 1991). "Since the ultimate burden of proving infringement rests with the patentee, an accused infringer seeking summary judgment of noninfringement may meet its initial responsibility . . . by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." Novartis Corp. v. Ben Venue Labs., Inc., 271 F.3d 1043, 1046 (Fed. Cir. 2001).

"Under modern summary judgment law, a patentee who fails to provide probative evidence of infringement runs the risk of being peremptorily nonsuited." Id. at 1051 (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)). "[A] party does not meet this evidentiary threshold merely by submitting the affidavit of an expert who opines that the accused device meets the claim limitations." Id.; Moore U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091, 1112 (Fed. Cir. 2000) (finding conclusory declarations alleging infringement of accused devices insufficient to carry patentee's burden of proving infringement, both literally and under the doctrine of equivalents). Rather, "the expert must set forth the factual foundation for his

opinion . . . in sufficient detail for the court to determine whether that factual foundation would support a finding of infringement under the claim construction adopted by the court, with all reasonable inferences drawn in favor of the nonmovant." Novartis Corp., 271 F.3d at 1051 (quoting Arthur A. Collins, Inc. v. N. Telecom Ltd., 216 F.3d 1042, 1047-48 (Fed. Cir. 2000) (alteration in original)).

## II. **BSC HAS FAILED TO PROVE INFRINGEMENT BY CONOR'S OTHER STENT DESIGNS**

The Court should grant summary judgment as to Conor stent designs other than the CoStar and UniStar designs. BSC's evidence of infringement or Conor's stent designs other than CoStar and UniStar falls short in three independent ways: (1) BSC failed to properly and timely identify the designs as accused stents; (2) BSC failed to show that the designs are in fact "products" that have ever been offered for sale or sold anywhere in the world; and (3) BSC's expert failed to offer a legitimate infringement analysis for any of the designs.

BSC failed to identify what designs other than CoStar and UniStar it is accusing of infringement. BSC never identified any stent designs other than the CoStar and UniStar designs during fact discovery – it did not identify any in its complaint and it did not identify any in its interrogatory responses. Indeed, BSC supplemented its contentions of infringement regarding the CoStar and UniStar stents on the last day of fact discovery, and neither supplemented the interrogatory concerning accused products nor added any discussion of other accused products to its infringement contentions. The closest it comes to any such identification is in Prof. Moore's expert report, where he refers to various drawings and pictures of stents and opines that they infringe claim 35 of the '021 patent:

certain related Conor stent designs (*see, e.g.*, CM 003282; CM 003292; CM 003295-96; CM 003319-20; CM 003321-22; CM 003364-65; CM 003366-67; CM 058215, CM 006890; CM 009886-87; CM 107551, CM 118758, CM 118760, CM 118767,

CM 118784, CM 118844-45, CM 118931, CM 123949, CM 123950, CM 124264, CM 125112; CM 020458; CM 058476-77; CM 090066; CM 119000; CM 129935 and BSC-C 85073) (*see* Exhibit C).

Ex. B ¶ 8(C).

Having failed to timely identify the designs, BSC may not accuse them of infringement by way of Prof. Moore's expert report. *See Kim*, 412 F. Supp. 2d at 933-34 (precluding evidence on products accused of infringement not identified in interrogatory responses on that issue even though responses stated that other products might be added after discovery); *see also Lucent Techs. Inc. v. Gateway, Inc.*, 2007 WL 925502, at \*3 (S.D. Cal. Mar. 19, 2007) (precluding party from asserting contributory infringement theory when party failed to disclose the theory in its interrogatory responses).

Moreover, the other designs Prof. Moore opines are infringing are drawings and pictures of stents that have never been commercialized as actual products sold anywhere in the world. He does not even suggest that all of these designs were ever made or used, and BSC offers no evidence that any of them were ever sold in the United States so as to even implicate any U.S. patent rights. *See Kaliardos v. Gen. Motors Corp.*, 777 F. Supp. 543, 548 (E.D. Mich. 1991) (granting summary judgment with respect to product identified in interrogatory responses as infringing for which plaintiff identified no sales by defendant); *LG Elecs. Inc. v. Q-Lity Computer, Inc.*, 211 F.R.D. 360, 370 (N.D. Cal. 2002) (denying motion to amend complaint to add products that defendant did not make or sell). BSC's own expert recognizes that only finished products, not mere engineering drawings, may be found to infringe. Ex. M at Tr. 171. Having not shown that the other stent designs first identified in Prof. Moore's expert report were ever commercialized in a way that infringes BSC's patent rights, summary judgment is proper.

Even if BSC had properly and timely identified the other designs and showed that they were commercialized in such a way to implicate U.S. patent rights, summary judgment of non-infringement would be proper. BSC offers no particularized proof of infringement for any of Conor's stent designs other than the CoStar and UniStar stents. The full extent of BSC's analysis of Conor's "related stent designs" comes from one conclusory paragraph of Dr. Moore's report:

Certain of Conor's related stent designs . . . similarly include alternating expansion columns connected to connector columns in the manner claimed by the Jang '021 patent. My infringement analysis regarding the CoStar stent is therefore equally applicable to at least these related Conor stent designs.

Ex. B ¶ 26. This is precisely the sort of conclusory evidence that courts have found insufficient to raise a triable issue of fact on infringement. See, e.g., Novartis Corp., 271 F.3d at 1054-55; Moore U.S.A., Inc., 229 F.3d at 1112; Arthur A. Collins, Inc., 216 F.3d at 1048; Eon-Net, L.P., 239 F.R.D. at 615.

Having not raised any triable issues of infringement as against the related stent designs, summary judgment of non-infringement against BSC is proper.

### **III. IF THE COURT ACCEPTS CONOR'S CONSTRUCTION OF THE WHEREIN CLAUSE, THE COSTAR STENT DOES NOT INFRINGE CLAIM 35 OF THE '021 PATENT**

#### **A. The CoStar Stent Has a 180 Degree Out-of-Phase Design and Does Not Connect Offset Expansion Strut Pairs in Adjacent Columns; It Therefore Is Outside the Scope of the Properly Construed Claim**

As demonstrated in the Markman brief that Conor is filing on this date, the proper construction of the "wherein" clause limits claim 23 to stents in which the first expansion struts of the (distally coupled) expansion strut pairs of the first expansion column are circumferentially offset from first expansion struts of the (proximally coupled) expansion strut pairs of the second

expansion column, thereby limiting the claim to stents with offset connected strut pairs and excluding stents with 180 degree out-of-phase design.

There is no dispute that the CoStar stent has a 180 degree out-of-phase design, with connectors linking expansion strut pairs that are aligned, on the same level and facing in opposite directions. Under the correct claim construction, claim 35 of the '021 patent does not cover that design. As a result, the CoStar stent does not infringe claim 35 under a proper claim construction. Summary judgment of no literal infringement is accordingly appropriate. See, e.g., K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1362, 1366-69 (Fed. Cir. 1999) (affirming grant of summary judgment of no literal infringement where the only issue was claim construction); Gen. Mills, 103 F.3d at 983-85 (same).

**B. BSC Is Barred By Prosecution History Estoppel from Asserting Infringement Under the Doctrine Of Equivalents**

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In addition, there can be no infringement under the doctrine of equivalents here. BSC is barred by amendment-based estoppel from asserting the DOE against the CoStar stent under Festo.

**1. The Filing of a Narrowing Amendment for Reasons of Patentability Creates a Presumption of Estoppel Under *Festo***

As the Supreme Court held in Festo, "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to estoppel." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002); see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359 (Fed. Cir. 2003) (*en banc*). Under Festo, amendment-based estoppel comes into play where there was a narrowing amendment for purpose of patentability.

The amendment adding the "wherein" clause to both of Jang's independent claims unquestionably was a narrowing amendment. It added requirements that previously were not



part of the claims, *i.e.*, a requirement that "the first expansion strut in the first expansion strut pair in the first expansion column has a longitudinal axis offset from the first expansion strut in the second expansion strut pair in the second expansion column." Ex. L, at JFH000205, 208.

Moreover, the amendment unquestionably was made for reasons of patentability. Festo, 535 U.S. at 736. The amendment was made in direct response to the Examiner's rejection of both of Jang's independent claims as anticipated by a particular 180 degree out-of-phase design (Pinchasik). Jang explained in his arguments to the PTO that the purpose of the "wherein" clause was to overcome the identified prior art. (*i.e.*, Pinchasik). Ex. L, at JFH000209.

## 2. BSC Cannot Overcome the *Festo* Presumption

Under Festo, Jang's amendment to both of his independent claims for reasons of patentability creates a rebuttable presumption that BSC surrendered all equivalents for the added limitation:

A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim.

Festo, 535 U.S. at 740.

Under Festo, a patentee can rebut this presumption of estoppel if he can show that one of the following criteria is applicable: (1) the alleged equivalent was not foreseeable at the time of the amendment; (2) the rationale underlying the amendment "bear[s] no more than a tangential relation" to the equivalent; or (3) there is "some other reason" suggesting that the patentee could not reasonably be expected to have described the equivalent. Id. at 740-41; see also Festo, 344 F.3d at 1369-70. BSC cannot satisfy any of these exceptions

The first Festo criteria applies where the alleged equivalent was not foreseeable at the time of the amendment. Festo, 535 U.S. at 740. That is not the case here. Stents with 180

degree out-of-phase stent designs were well-known at the time Jang amended his claims to exclude such stents. Indeed, Jang cited one in the '021 patent specification. '021 patent, col. 2, lines 40-44, 57-65.

The second Festo criterion, the "tangential relation" criterion, "focuses on the patentee's objectively apparent reason for the narrowing amendment" as manifested in the prosecution history. Festo, 344 F.3d at 1367-70. The rationale for an amendment is only "tangentially" related to the alleged equivalent if it is "peripheral" or "not directly relevant" to the equivalent. Id. at 1369 ("tangential" means "the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent") Thus, "an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim." Id.; see also Talbert Fuel Sys. Patents Co. v. Unocal Corp., 347 F.3d 1355, 1360 (Fed. Cir. 2003); Chimie v. PPG Indus., Inc., 402 F.3d 1371,1383 (Fed. Cir. 2005).

BSC cannot show that the rationale underlying its amendment bears no more than a tangential relation to the alleged equivalent. To the contrary, the "wherein" clause amendment was made specifically for the purpose of avoiding Pinchasik, a 180 degree out-of-phase stent design. Ex. L at JFH 196. As Conor's stents have that very structure, BSC cannot show that the amendment is only "tangentially" related to Conor's stents. Festo, 344 F.3d at 1369.

The third Festo criterion applies where there is "some other reason" suggesting that the patentee could not reasonably be expected to have described the equivalent. Festo, 344 F.3d at 740-41. As the Federal Circuit has made clear, this criteria "must be a narrow one." Festo, 344 F.3d at 1370. BSC cannot satisfy this criteria here.

**3. Summary Judgment of Noninfringement by Equivalents is Appropriate Under *Festo***

Because the "wherein" clause represents a narrowing amendment for reasons of patentability under *Festo*, and because BSC cannot rebut the presumption of amendment-based estoppel under *Festo*, summary judgment of noninfringement under the DOE is appropriate. See *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1357 (Fed. Cir. 2004) (affirming summary judgment of no DOE infringement under *Festo*); *Bus. Objects, S.A. v. Microstrategy, Inc.*, 393 F.3d 1366, 1374 (Fed. Cir. 2005) (same); *USA Video Tech. Corp. v. Movielink L.L.C.*, 354 F. Supp. 2d 507, 521-22 (D. Del. 2005).

**CONCLUSION**

For the reasons set forth above, this Court should grant Conor's motion for summary judgment: (1) that its stent designs other than the CoStar and UniStar stent designs do not infringe claim 35 of the '021 patent, and, if the Court adopts Conor's proper construction of the wherein clause, (2) that the CoStar and UniStar stents do not infringe claim 35 of the Jang '021 patent.

ASHBY & GEDDES

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Dated: May 11, 2007  
180501.1

**CERTIFICATE OF SERVICE**

I hereby certify that on the 18<sup>th</sup> day of May, 2007, the attached **REDACTED PUBLIC VERSION OF OPENING BRIEF IN SUPPORT OF CONOR MEDSYSTEMS' MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT OF CLAIM 35 OF THE JANG '021 PATENT** was served upon the below-named counsel of record at the address and in the manner indicated:

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**HAND DELIVERY**

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**VIA FEDERAL EXPRESS**

*/s/ Lauren E. Maguire*

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Lauren E. Maguire